

AV-VITE FB FORTE - pyridoxine hydrochloride, folic acid, and cyanocobalamin tablet, coated
AvKARE, Inc.

Av-VITE FB Forte
Prescription Dietary Supplement

DESCRIPTION: Av-VITE FB Forte Tablets are an orally administered prescription dietary supplement for the management of patients requiring increased folate levels.

Av-VITE FB Forte Tablets should be administered under the supervision of a licensed medical practitioner.

Supplement Facts		
Serving Size: 1 Tablet		
	Amount Per Serving	% Daily Value
Vitamin B₆ (as Pyridoxine HCl)	25 mg	1250%
Folic Acid	2.5 mg	625%
Vitamin B₁₂ (as Cyanocobalamin)	2 mg	33333%

Other Ingredients: Dibasic Calcium Phosphate Dihydrate, Microcrystalline Cellulose, Opadry II Beige 40L17427 (Titanium Dioxide, Polydextrose, Hypromellose 3cP, Hypromellose 6cP, Triacetin, Hypromellose 50cP, Polyethylene Glycol 8000, FD&C Yellow # 6 Aluminum Lake, FD&C Blue # 2 Aluminum Lake, FD&C Red #40 Aluminum Lake), Croscarmellose Sodium, Opadry II Clear #Y-19-7483 (Hypromellose 6cP, Maltodextrin, Hypromellose 3cP, Polyethylene Glycol 400, Hypromellose 50cP) Magnesium Stearate.

Contains: FD&C Yellow #6 Aluminum Lake, FD&C Blue #2 Aluminum Lake, FD&C Red #40 Aluminum Lake

ALLERGY STATEMENT: This product has been manufactured in a facility that also manufactures products containing milk and soy. Individuals with allergic tendencies to these substances should use discretion.

Allergic reactions have been reported following the use of oral folate.

Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body have been associated with cobalamin.

Paresthesia, somnolence, nausea, and headaches have been reported with pyridoxine.

CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the components contained in this product.

CAUTION: High levels of folic acid may, especially in older adults, hide signs of vitamin B-12 deficiency (such as pernicious anemia), a condition that can cause nerve damage.

INTERACTIONS: Drugs which may interact with folate include but are not limited to:

- First generation anticonvulsants (folate may reduce their effectiveness)
- Capecitabine (folate may enhance its toxicity)
- Fluorouracil (folate may enhance its toxicity)

Drugs which may interact with folate metabolism include, but are not limited to:

- Dihydrofolate Reductase Inhibitors
- Fluoxetine
- Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
- Sulfasalazine
- Warfarin

Drugs which may interfere with the absorption of folate from the gastrointestinal tract or decrease plasma levels include, but are not limited to:

- Cholestyramine
- Colestipol
- Oral Contraceptives
- Methylprednisolone
- Pancreatic Enzymes
- Pentamidine
- Smoking and Alcohol
- Sulfasalazine
- Metformin

Drugs which may interact with vitamin B₆ include, but are not limited to:

- Levodopa (the action of levodopa may be antagonized by vitamin B₆)

Drugs which may interact with vitamin B12 include but are not limited to:

- Antibiotics, cholestyramine, colchicines, colestipol, metformin, para-aminosalicylic, and potassium chloride (may decrease the absorption of vitamin B12).
- Nitrous oxide (can produce a functional vitamin B12 deficiency).

PREGNANCY and NURSING MOTHERS: Av-VITE FB Forte Tablets are not intended for use as a prenatal/postnatal multivitamin for lactating or nonlactating mothers. This product contains only B vitamins. Talk with your medical practitioner before using if pregnant or lactating.

DOSAGE AND ADMINISTRATION: One to two tablets daily or as directed by a licensed medical practitioner.

STORAGE: Store at room temperature 15° to 30°C (59° to 86°F).

HOW SUPPLIED: Av-VITE FB Forte Tablets are round, coated, beige colored tablets imprinted on one side with "V201", and are supplied in bottles of 90 tablets NDC 42291-151-90.

KEEP THIS OUT OF REACH OF CHILDREN.

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

Call your medical practitioner about side effects.

You may report side effects by calling AvKARE, Inc. at 1-855-361-3993 or FDA at 1-800-FDA-1088.

Manufactured for:
AvKARE, Inc.
Pulaski, TN 38478

Mfg. Rev. 06/15
AV 04/16 (P)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**AvKARE****NDC 42291-151-90****Av-VITE FB Forte**

Prescription Folic Acid-Containing Dietary Supplement

90 Tablets

Must be used under the supervision of a physician.

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DESCRIPTION: Av-VITE FB Forte is an orally administered prescription dietary supplement and should be administered under the supervision of a licensed medical practitioner. See package insert for complete product information.

DIRECTION FOR USE: 1 or 2 tablet(s) daily or as directed by a physician.

WARNING: Keep this and all medications out of the reach of children.

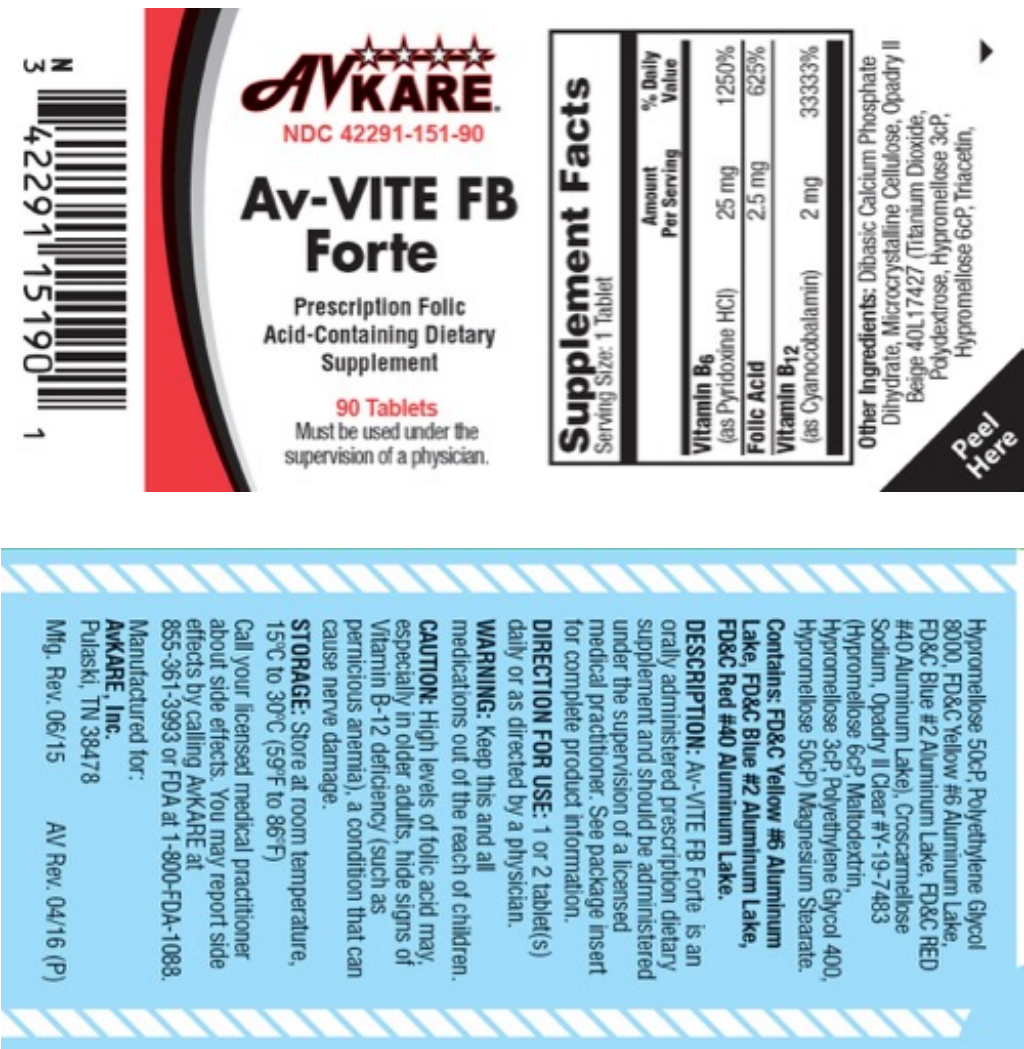
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Mfg. Rev. 06/15 AV 04/16 (P)



AV-VITE FB FORTE

pyridoxine hydrochloride, folic acid, and cyanocobalamin tablet, coated

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRC:4229 1-151(NDC:76439-365)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
PYRIDOXINE HYDROCHLORIDE (UNII: 68 Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)		PYRIDOXINE HYDROCHLORIDE	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)		FOLIC ACID	2.5 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)		CYANOCOBALAMIN	2 mg

Inactive Ingredients				
Ingredient Name			Strength	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
Titanium Dioxide (UNII: 15FIX9V2JP)				
Polydextrose (UNII: VH2XOU12IE)				
TRIACETIN (UNII: XHX3C3X673)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
ALUMINUM OXIDE (UNII: LMI26O6933)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
Croscarmellose Sodium (UNII: M28OL1HH48)				
Maltodextrin (UNII: 7CVR7L4A2D)				
Magnesium Stearate (UNII: 70097M6I30)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42291-151-90	90 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT			11/05/2015	

Supplement Facts		
Serving Size :		Serving per Container :
	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	9 mm	
imprint		

Labeler - AvKARE, Inc. (796560394)